PCRM PHYSICIANS COMMITTEE FOR RESPONSIBLE MEDICINE
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December 7, 2001

The Honorable Christine Todd Whitman
Administrator
U.S. Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

Subject: Comments on HPV Test Plan and Robust Summaries for Acetoacet-o-anisidide

Dear Administrator Whitman:

The following comments on the test plan for acetoacet-o-anisidide are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than nine million Americans.

The test plan for acetoacet-o-anisidide, submitted by the Color Pigments Manufacturers Association, Inc.'s Diarylide Intermediates Task Force, presents information that satisfies each of the SIDS endpoints and appropriately does not call for additional testing. Furthermore, acetoacet-o-anisidide is manufactured and transported in closed systems and has limited commercial availability. Exposure to this chemical is highly unlikely, and any additional testing would not expand the understanding of this chemical or change how it is handled. Therefore, we support the conclusion that no further testing on animals is warranted. However, we suggest that the information presented in the test plan would be enhanced if it were presented as a category analysis.

Although the Color Pigments Manufacturers Association, Inc., presents this test plan for an individual chemical, the analysis draws on existing toxicological data from two other HPV chemicals. Therefore, this test plan should really be presented as a category analysis. The Color Pigments Manufacturers Association, Inc., is using existing information from structurally similar HPV chemicals acetoacet-o-anisidide (CAS# 92-15-9), acetoanilide (CAS# 102-01-2), and aceto-o-toluidide (CAS # 9368-5) and should include these three chemicals in its assessment. Presentation of a chemical category provides greater insight into the relationship between chemical structure and toxicity and provides the opportunity for reducing testing.

Moreover, the October 1999 Agreement among the EPA, industry, animal protection organizations, and environmental groups states, in part, "Participants shall maximize the use of scientifically appropriate

categories of related chemicals and structure activity relationships." This is important because a category analysis could obviate the need for testing with acetoanilide and aceto-o-toluidide in the future.

Thank you for the opportunity to comment. I can be reached at 202-686-2210, ext. 302, or via e-mail at *ncardello@pcrm.org.* Correspondence should be sent to my attention at PCRM, 5100 Wisconsin Ave., N.W., Suite 400, Washington, DC 20016. I look forward to your response on these important issues.

Sincerely,
Nicole Cardello, M.H.S.
Staff Scientist